



BIOTECHNOLOGY  
INDUSTRY  
ORGANIZATION

January 24, 2005

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Agency Information Collection Activities; Guidance on  
Consultation Procedures; Docket No. 2004N-0503

To Whom It May Concern:

This letter is submitted by the Biotechnology Industry Organization (BIO), in response to the notice of agency information collection activities published by the Food and Drug Administration (FDA) in the Federal Register on November 24, 2004 (69 Fed. Reg. 68379). BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products, including biotechnology-derived crops.

BIO applauds FDA's commitment to a science-based review process consistent with any potential risk that might be posed by food derived from new plant varieties. We would also like to renew our support for the pre-market biotechnology notification (PBN) rule proposed by FDA on January 18, 2001 (66 Fed. Reg. 4706). In particular, BIO urges FDA to finalize that rule at the earliest possible time.

The PBN Rule would formalize a procedure for the submission and review of pre-market notifications for biotechnology-derived foods, enhance the transparency of the review process and address FDA's enforcement authority as it applies to biotechnology-derived food that might be marketed without satisfactory completion of the PBN process. Prompt action to finalize the PBN Rule is needed to further strengthen U.S. government policy related to biotechnology, reassure the public, food and commodity groups, agricultural interests and food export markets of the safety of all biotechnology-derived foods grown in the U.S., and to ensure the safety of the domestic food supply, particularly with respect to future imports from developing nations.

2004N-0503

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C 1

Letter to FDA regarding Docket No. 2004N-0503  
January 24, 2005  
Page 2

We appreciate the opportunity to provide comments on this information collection activity.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael J. Phillips". The signature is fluid and cursive, with a large initial "M" and a distinct "P".

Michael J. Phillips, Ph.D  
Vice President  
Food and Agriculture  
Science and Regulatory Policy